FINAL TRANSCRIPT

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Event Transcript

BPUR - Q3 2003 Biopure Corporation Earnings Conference Call

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PRESENTATION

Operator

Good afternoon. My name is Jeff and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Biopure third quarter fiscal 2003 earnings conference call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer period. (OPERATOR INSTRUCTIONS) I would now like to turn the conference over to Douglas Sayles, Director of Corporate Communications. Please go ahead, sir.

Doug Sayles - *Biopure Corporation - Corporate Communications*

Good afternoon everyone and welcome to our third quarter 2003 conference call for the period ending July 31st. Today we'll report our financial results for this period and briefly discuss some of the company's accomplishments and activities after which we'll answer a few questions. Before we begin, I'd like to point out that during this call we'll make projections and other forward-looking statements which involve risks and uncertainties that could cause the company's actual results or performance to differ materially from those projected. The condensed list of these respective factors appears at the end of today's financial results press release which you can access on the Internet. A more comprehensive discussion occurs on our SEC filings and at Biopure.com. Now I'd like to turn the call over to our CEO and President, Tom Moore.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Good afternoon everybody and thanks for joining us. I'm joined around this table, in addition to Doug, by Ron Richards, our Chief Financial Officer and Senior Vice President of Business Development; and Dr. Howard Richman, who is, as you know, our Senior Vice President of Regulatory Affairs and Operations. We feel very positive about our third quarter results from both a financial and general business standpoint. Our loss was $11.3 million compared to $12.6 million in the same period last year. This translates to a loss of 28 cents per share compared to 43 cents a share a year-ago. With Oxyglobin revenues of $885,000, up significantly from $260,000 a year-ago, we clearly are revitalizing this business after paralyzing product shortages in 2002. We also introduced our first new Oxyglobin SKU, the 60 millimeter size bag, which is off to a strong start with $200,000 sales in just its first three weeks of availability. This smaller size is more convenient and offers better economics to our veterinarian customers, but is also a higher profitability SKU for us.

Most importantly, we've made another big step forward on our regulatory review of Hemopure by FDA. On July 30th, the agency informed us they had completed review of our application and sent us all the questions that need to be answered for them to progress to an action letter. The agency has done us a big favor by providing what amounts to a complete detailed response and set of questions to Biopure prior to the end of the review cycle, and then stopping the review clock with 30 days remaining in the PDUFA cycle. They have thereby made a commitment to give us an action letter 30 days after we provide our response to their questions. They could have just as easily announced an end to the review cycle with their response, in which case they would've had two to six months to respond to our answers instead of the 30 day period.

We've completed our initial response preparations and will now formally request a meeting with FDA. Both Biopure and the

FDA have been informally clearing our calendars for this meeting over the past week in order to expedite our get-together. This meeting will allow us to request any clarification we need to ensure that our complete response fully meets the agency's needs. We went to make the most of this opportunity to work with the agency towards early action. Our efforts to date suggest that we're in good shape so far to be able to answer FDA's questions. However, we're still collecting some data, so the job is not yet complete. We are well down the preparation track on questions related to our trials, Pharmokinetics (ph), immunology, labeling and the like. However, there are some questions, such as questions related to historical data from our clinical sites, that precedes the actual running of our trials which could take some time to collect. We hope the FDA will agree to reduce the scope of some of these requests. In the end, the exact timing of our FDA response will be driven by our interaction with FDA in this meeting which we expect to have occur in September.

In a separate area, we're pleased by investor response to the company over the past three months. In July we completed a public offering raising $17.2 million on what we believe are very attractive terms, namely only a 5 percent discount to the market with no warrant coverage. These terms are the best terms for a public offering for any biotech company with a market cap of $1 billion or less this year as of two weeks ago. We believe this also shows that we've achieved a degree of financial maturity as a potential investment opportunity. In conducting this raise, Chief Financial Officer Ron Richards and I presented to 62 funds in person over a three-week period. This is the most extensive presentation of the company ever, surpassing even the effort behind the IPO launch. Subsequent share price performance suggests we're beginning to establish an understanding of the exciting future potential for Hemopure as both a treatment for anemia associated with surgery, and an oxygen therapeutic for use in trauma, surgical ischemias and cancer therapy.

Finally, while we're discussing the stock, we have received numerous calls concerning insider trading activity over the past few days. Because of the flood of forms that are being filed are confusing, I do want to take this opportunity to clarify just exactly what's going on. Our co-founder and Chief Technology Officer, Carl Rausch, is continuing to sell a relatively small portion of his Biopure holdings in order to meet his personal financial needs. He publicly announced his intent to do so, in fact, some time ago. While about 350,000 shares have been sold over the last year, Carl is still the direct or indirect holder of more than 1,600,000 Biopure shares.

Two other factors have made insider reporting a little confusing. First we've had to update an error in Form 4 reporting on shares indirectly controlled by Mr. Rausch dating back to the year 2000. Unfortunately, each Form 4 since then has had to be revised separately, so this has led to a proliferation of amendments. And finally, there have been some small inter director sales -- shares exchanged with no net selling of shares. In fact, the company has locked up these shares until September -- I'm sorry, until spring 2004. Of all the company's officers and directors, only Carl Rausch has sold Biopure shares to outsiders over the past several months.

I want to update you briefly on our medical communications campaign as well which we touched in our last call. Briefly, in early June, Hemopure investigator Dr. Jonathan Yar (ph), who is a Professor of Clinical Anesthesiology and Director of Clinical Research at the Department of Anesthesiology at UCLA, and Doug Hansell, our Vice President of Medical Affairs, gave separate Hemopure related presentation to the regional medical directors of the American Red Cross. On June 6th, Biopure sponsored an investigator and thought leader meeting entitled clinical experience with Biopure which was chaired by Colin McKenzie, Vice Chair of Anesthesiology at the Adams Shock Trauma Center in Baltimore, Maryland. On June 13th, our Senior Vice President, Maria Gawryl, discussed the status of Hemopure during a blood substitutes workshop at a joint conference of the American Society for Artificial Internal Organs and the International Society for Artificial Organs in Washington D.C.

And the next day, on the 14th, Biopure sponsored an open symposium on the clinical experience with Hemopure at the Network for Advancement of Transfusion Alternatives in San Francisco moderated by Dr. Lawrence T. Goodnough, Professor of Medicine Pathology and Immunology at Washington University in St. Louis. On July 26th, Dr. Hansell also presented a Hemopure overview to the regional medical directors of America's Blood Centers at their Scientific, Medical and Technical Forum in Spokane, Washington. And then earlier this week, Nora Philbin (ph) an investigator at the Naval Medical Research Center in Bethesda, Maryland, presented results of an NMRC preclinical study of Hemopure entitled Improved Tissue Oxygenation After Bovine Prelimerized Hemoglobin Resuscitation in a Slide Hemorrhagic Shock at the annual meeting of the International Society on Oxygen Transport to Tissue at the University of Rochester in New York.

And then in early September, Dr. Ian DeVosse, a South African orthopedic surgeon and Hemopure clinical investigator, will present data from the Hemopure Phase III trial at the annual

South Africa Orthopedic Surgical Congress in Cape Town, South America -- South Africa, excuse me. We also have recently had a new publication on our product on expert opinion on biological therapy concerning the use of our product as an Oxygen Bridge in patients with acute anemia associated with surgical blood loss penned by Dr. Leavy (ph). Other study articles are being submitted by numerous Hemopure investigators, and so you can expect a strong level of scientific exchange activity in the months ahead. Those are my overview comments. We would now welcome your questions.

QUESTIONS AND ANSWERS

Operator

(OPERATOR INSTRUCTIONS) Jason Colbert of Susquehanna Capital.

Jason Colbert - *Susquehanna Capital - Analyst*

Hi, Tom. Very exciting company in recent events at Biopure. A couple of questions on the letter from the FDA. You used the term complete response a couple of times. But, this isn't a complete response letter. What is it exactly?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

It's, and I'll ask Howard Richman to comment on this in just a second. It is -- I think Howard will call it a hybrid, and by that I mean it genuinely represents all the questions that FDA would like to have us answer, and so in that sense it's like a complete response. But normally a complete response letter brings an end to the review cycle. And the agency has elected not to do that, offering us this precious opportunity to get a response 30 days after we submit the answers to those questions. And so, that's what it is.

Jason Colbert - *Susquehanna Capital - Analyst*

It sounds like the response is going to take some time. Can you tell me about how many questions are involved? And the follow-up question is, depending on the length of your response, is it reasonable to expect that the FDA is going to be able to respond back within that 30 day timeline? If you give them a very exhaustive detailed response back, as I know you will, isn't it going to take the FDA longer than 30 days to respond back?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

I think that's a very fair question, and that's one of the motivations we have for having a meeting with FDA simply so we can agree on how we're going to order this data and maybe how we can share some of the data as we go so that it makes it easier for them to meet that guideline.

Howard Richman - *Biopure Corporation - Senior VP, Regulatory and Operations*

I'll share this with yourself and for the other people listening. This type of letter is very unique. As Tom clearly stated for everyone, it is a hybrid, it's something that was done from the (indiscernible) perspective to work with Biopure in this aspect because you're right in stating that people have (indiscernible), this does not follow the area that we've seen where you look on FDA sites or in other complete responses. This was done with the specific intent to work with us. With that being said, it counts in such a way that they want us to be able to get back to them vis-a-vis this meeting and in our answers. Many of our answers will not be that detailed in response, some are in clarification, which will only meet the FDA with some points we're going to discuss with them. Other ones will just provide them information they requested in terms of clarification and follow-up source documents and other information they've asked about. So, when you say about a detailed (indiscernible) response, in many ways it will not be. But it's also clear that the format that they have for us with FDA which will be clarified on a meeting in September will clearly enlighten us and them and give a clear pathway to the response in a correct time frame.

Jason Colbert - *Susquehanna Capital - Analyst*

Okay. Thanks, guys.

Operator

Sapna Srivastava of ThinkEquity Partners.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Hi, Tom, how are you? A couple of questions. I guess I'm just expected -- you mentioned some of the historical data may take more time to collect, could you just give us some color on what historical data is being asked for, and what is your best guess of the time that you can put forward for these responses? Best case scenario, worst-case scenario?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Sure. I'll give you an example. The FDA requested blood transfusion records from our clinical sites which would extend back a year prior to when our study began. An example of sort of the background nature of many of these questions which actually don't relate to the specific clinical data we collected. Collecting historical transfusion records from that many sites is a bit of an intimidating task, and so we actually don't know how long it would take, but we know it's going to take more than an afternoon of phone calls to bring all those records safely back in. That's one particular area we want to dialogue with FDA to see if there isn't a way we can meet their needs without literally fulfilling the terms of this particular request.

Your backup question of that was so what does that mean in terms of the duration of getting all of this to happen? And I guess I have to frankly say I just don't know because I don't know how long it actually would take to hire four or five people, train them, and then get them on the planes with suitcases to actually go off and retrieve these records. That's one of the unknowable things that came out as we looked more and more closely at the nature of FDA's request and the mechanics of what it would take to really get that request fulfilled.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Can you help me understand, what do they do with blood transfusion records at clinical sites?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

I'm sorry, Sapna, I didn't quite understand your question.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

I just -- what does the FDA -- why do they require data (indiscernible) -- historical data from these clinical sites like blood transfusion records? What does it go towards?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

I think they're looking to see what the pattern is of the decisions to transfuse. And I think they're interested in getting some background data on how medicine is being practiced in various places. I don't know if Howard would alter or add to that response.

Howard Richman - *Biopure Corporation - Senior VP, Regulatory and Operations*

Just one (indiscernible) quite clearly. But just one thing for information. It's (indiscernible) of the uniqueness of this product that will set the standard for other products coming behind it, the FDA has asked for this information so they'll be able to help Biopure in this approval process and other companies that will come down the same path as to what really are the transfusion requirements as they see in the orthopedic and/or surgical indications that will put the patients in the best possible place in terms of unit dosing. It's not an unreasonable request, it's just something that needs clarification. Does that help you?

Operator

Alan Ferguson of 3i Technology Partners.

Alan Ferguson - *3i Technology Partners - Analyst*

Hi, Tom. I'd like to get some understanding of where Biopure stands in terms of approval in other countries?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Good afternoon, Alan. We -- as we talked in our last quarterly, we are exploring doing filings elsewhere around the world. We have had discussions with regulatory agencies to line up on what their requirements would be for a submission to check that datafile that we've collected, working with FDA will be sufficient for approval in other areas. And I think we indicated that we would be sharing more news about international filings before year end. So that's an active area. We don't currently have an application pending anywhere else in the world.

Operator

Sapna Srivastava.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Sorry, I think we got disconnected. I still wasn't done.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Don't worry about that. We're very happy to have you reconnected.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Actually I just still wanted to get a better understanding about the focus. So the blood transfusion record, is that the largest part of the questions that the FDA has given to you or the most time-consuming?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

It's the most time-consuming question because it requires going off and getting data significantly. Frankly, like many of the questions that the FDA asks, it doesn't require any reanalysis of our data, it's more documentation, more information gathering of a background nature than anything else.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Is it something that you can (indiscernible) postmarketing registry, is that something you can do rather than having to delay it for approval?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

It's the kind of thing that at least you can discuss with the agency, and that's why we think this meeting -- it's one of the aspects of the meeting we think could be very helpful in terms of streamlining the actual action process.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

And this meeting is going to be sometime in September, you don't have a date yet?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

That's correct.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Just on a little different topic, a couple more questions. You mentioned some new data on Hemopure coming up or did I misunderstand that?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

We're going to the new publication on Hemopure.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Okay. And the last question is just, how is the use in South Africa going, what's the update there?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Product continues to the used off the amount that we put in to be used on a more or less of a donated basis. In our press release we mention the fact that, thanks to Howard's efforts, we have gotten the product in hand and have extended expiration date, so we're able to work -- continue to work off that initial donated amount of product. We are working to unwind our business relationship with our previous partner there and start a new one. And that process is in the lawyer to lawyer discussion phase.

Sapna Srivastava - *ThinkEquity Partners - Analyst*

Okay. Thank you so much.

Operator

Richard Adams of Bennett Lawrence.

Richard Adams - *Bennett Lawrence - Analyst*

Just to repeat a question from earlier that I didn't hear an answer to which was the number of questions in the FDA letter. Can you tell us that?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

We probably aren't going to disclose that. I guess I shouldn't say probably. The number of questions isn't going to do very helpful to people to understand what's really in the letter. As Howard indicated earlier, some of the questions are as simple as send us a list of this or send us the name of that. Things like that. So, as we look at it, there are a number of questions involved. What I will say is there's probably about 50 substantive questions which we have -- which we're working on which are really the core of the efforts that we're doing now. So, I think the number 50 is more useful to bear in mind than the list of a lot of the stuff they have we've just run to the copier, copy it and throw it in the stack. But there are 50 things that we've got to work on to give them what we think will be a complete response.

Richard Adams - *Bennett Lawrence - Analyst*

Have you been assured by the FDA that once you answer the 50 questions that they can issue an action letter or is the potential that you satisfactorily answer let's say 40 of them and you have to go back and the process extends indefinitely?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

That's impossible to say. The FDA doesn't give us that kind of hand holding. Their approach is here are the questions, answer them as best you can, and based on that we will give you our answer. Obviously one of the advantages of having a meeting with the FDA is you can kind of reaffirm with them what are pivotal questions and what are nice-to-knows, what could be prioritized in what way, and that's one of our objectives in the discussion coming up in September.

Richard Adams - *Bennett Lawrence - Analyst*

And the September meeting, did the FDA request a meeting or did Biopure?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Biopure requested the meeting, FDA agreed that we could set the agenda for the meeting, and then further that they didn't need to ask us any additional questions so that basically the discussion will revolve entirely around the clarifications that Biopure is going to request.

Richard Adams - *Bennett Lawrence - Analyst*

Okay. One last quick one. Do you expect to need to raise capital again before getting a definitive answer from the FDA?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

I think the answer is, in my opinion I don't think we'll need to do any kind of significant raise before we get an answer from FDA, that's my opinion. But because I can't -- one can never be entirely sure of the timeline, at least until we have the discussion with the FDA, I can't issue a guarantee on that, Richard. I just think -- I think we're in decent shape given the frame that I'm thinking of.

Richard Adams - *Bennett Lawrence - Analyst*

Okay. Thanks.

Operator

Alan Ferguson of 3i Technology Partners.

Alan Ferguson - *3i Technology Partners - Analyst*

Tom, can you comment in terms of where you are relative to the pricing strategy? Is this product going to be priced more like a Procrit or is it going to be priced more like a unit of pack sales?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

As you would expect, Alan, the answer is no. Meaning, I think we will be priced between -- I guess a does of Procrit is about -- Procrit is about $400 a shot, would you agree? So we'll be priced above Procrit, we'll be priced above packed red blood cells, but we'll be priced within a range of those prices that from a pharmacoeconomic standpoint as well as a therapeutic standpoint we represent an attractive alternative.

Alan Ferguson - *3i Technology Partners - Analyst*

Okay. Is there anything on the work the trials that the military is doing in trauma yet?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

We've not initiated human clinical trials in trauma with the military or for that matter on the civilian side as yet. So, we hope to get started on that ASAP. I think probably those trials will begin, however, at least after we have -- no sooner than after we filed our responses with FDA on the BLA questions. As I mentioned earlier in my flurry of discussions about meetings, Naval medical research has been very active in doing preclinical work on trauma with our product, and then sharing those results in several different forms actually. So, work is going on very actively on the trauma side, but I don't believe human trials will begin until after we have completed our answers to the BLA. Part of this is related to the fact that we already are engaged in FDA in a dialogue on a total clinical development program in trauma with FDA. And so we expect the final discussion on that with FDA will ensue after we've addressed the questions they've asked for us on the use in anemia from surgery indication.

Operator

Jason Colbert of Susquehanna Capital.

Jason Colbert - *Susquehanna Capital - Analyst*

Hi, Tom, me again. A couple more questions I'd like to explore with you. What's the manufacturing plan and the status of Sumter Realty? I wonder if you could touch on that? And kind of in sync with that, what are you thinking in terms of a partner strategy and how are those discussions going?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

From a manufacturing standpoint, as you know, our Cambridge facility here has a capacity for about 75,000 units per year. We already know how we can upgrade that capacity to a range between 90,000 and 100,000 units a year. It will require the implementation of a variety of process upgrades while most of the capital is in place there's still a little bit of work here and there that needs to be done, and our aim is to get that accomplished some time over the next six to nine months. The next step, as you know, is the construction of our Sumter facility in Sumter, South Carolina which will have a capacity of 500,000 units a year. We have -- we continue to be in negotiations for the financing for that facility. We're looking to get financing of $120 million on terms which would basically not require a net capital outflow from Biopure until the plan -- the plant is substantially complete, or i.e. in at least two years from now.

So, we're looking for very attractive financing terms. We don't negotiate directly for the financing, rather it's conducted through an LLC, it's called the Sumter Realty group. The Sumter Realty group has informed us that they're in negotiations with two different groups. They feel they're making progress, but as yet they have not set a date where we actually could sit down and sign the papers. And realistically, until we sign the papers, Jason, I don't think I can tell you the deal is done. But we are going to inform our investors when we feel that we're in fact moving in on a closing. But, it seems premature to make an announcement in that regard at this time.

Jason Colbert - *Susquehanna Capital - Analyst*

Is there a strategy, Tom, as you progress with the FDA towards partnership?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Here's our thinking on partnership. We have had very preliminary hi, how are you kind of discussions with some other companies. We have not pursued any partnership negotiation with, at least domestically, with any major pharmaceutical entity. Principal reason for that is for our initial indication in orthopedic surgery, and with our initial marketing plan which we've shared in the past where we'll be focused initially on bloodless surgery, we don't really need the kind of scope and experience that a pharmaceutical company would bring us, rather we need a tremendous focus on that indication and the ability to train deeply and vertically within the hospital medical center environment, that's something you don't get when you borrow a salesforce from another pharmaceutical company.

So, for the initial indication, we don't think there's going to be a great deal of synergy in working with another pharmaceutical firm at the initial launch step. On the other hand, as we look down the road for major additional indications for the product, I'll pick one entirely at random, Jason. Our use as a tissue sensitizer in the radiation and chemotherapy of solid cancer tumors like lioblastoma, liver cancer, pancreatic cancer and non small cell lung cancer, there it's not hard to see that potentially a partnership with a major cancer company could significantly accelerate the clinical development program and the introduction of our product as an additional tool in the war against cancer.

So, what I'd say is, Jason, we're developing sort of a differentiated strategy of how we would partner with this product in a way that we think is going to maximize shareholder value and not give away partial ownership in the company or rather on the product on a premature basis before we're able to fully show what the value of the product really is.

Jason Colbert - *Susquehanna Capital - Analyst*

Thanks, Tom. One last question, and this is on a completely different tact. It has to do with the Pivotal Phase III study, the published paper that Sar Stewart McKenzie Burke Williams did. In that study there's a section on serious adverse events, particularly respiratory failure where it shows four serious events in the HBOC-201 group versus zero in the RBC group. And I just wondered if there was any explanation? Is the explanation related to data slicing and age cohorts in the different arms?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Just a second, I'm getting advice on this one. Our analysis of that study shows that the four patients involved already had underlying respiratory disease. So, I think at this point at least, my response to your question is we think it has to do with pre-existing conditions. I can say for sure that when you look across the total body of clinical data on our product, there was no indication whatsoever of any association of our product with respiratory collapse of any kind.

Jason Colbert - *Susquehanna Capital - Analyst*

And does the FDA take that approach where they go into an individual patient record when there's a statistical anomaly and try to explain it in that format?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Yes.

Jason Colbert - *Susquehanna Capital - Analyst*

Thank you very much, Tom.

Operator

Adnan Butt of ThinkEquity Partners.

Adnan Butt - *J.P. Morgan Chase - Analyst*

Congratulations first of all on all the positive headway you've been making. I just had a question about use in South Africa. I'm wondering how closely you're tracking use whether it's in terms of safety or efficacy? And if it is being tracked will that be presented any time anywhere even if it's in the form of a case report or a letter to the editor or something like that?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

We are tracking it very closely. We tracked it initially, the way the product was initially introduced in the country was under what's called a Section 21 provision. And under the rules of Section 21 we actually present a report to the South African government on how the product was used, what its effectiveness was and what its safety was. And we've completed and filed that report. And frankly I would love to share that report more broadly, it paints I think a very positive picture of this product and the like. Since the Section 21 provision lapsed, we're now basically just a free sale product in South Africa, but we have our own special safety monitoring program so that we can share more or less of a Phase IV kind of fashion with both the Medicines Control Counsel in South Africa as well as FDA as well as any other regulatory agency that cares to know. But the actual experience has been the use of the product in general. And I can tell you, it's a very positive picture.

Adnan Butt - *J.P. Morgan Chase - Analyst*

But they are no plans to present it formally anywhere once you've started selling it?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Actually I can't tell you there is a plan to do so. We're -- or more accurately, what we're exploring is how we can publish this through a peer review journal so it will have the scientific standing that it deserves. And so that's what we're looking at doing right now.

Adnan Butt - *J.P. Morgan Chase - Analyst*

And any timing on that or just still in the planning stages?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

It's sort of in the advanced planning stages, but unfortunately I can't give you a commitment at this time as to when it will occur.

Adnan Butt - *J.P. Morgan Chase - Analyst*

Thank you, that's very helpful.

Operator

Gabe Hoffman (ph) of Accipiter (ph) Capital Management. Gabe, your line is open. Please go ahead with your question. That question has been withdrawn. Your next question comes from Richard Adams of Bennett Lawrence.

Richard Adams - *Bennett Lawrence - Analyst*

I'm just curious as to whether you're planning to present the full Phase III data set at a medical meeting sometime in the

future? I would think that that could help you Hemopure gain traction in the U.S.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

We are actually working to put a complete report on the 115 trial. The 115 trial. We're aiming to publish that in a major medical journal. We're in the process of submitting that article now. We also are looking for an opportunity to publish a complete data set for the product in the next year or so, but as yet we haven't identified the publication for that.

Doug Sayles - *Biopure Corporation - Corporate Communications*

There have been presentations of the Phase III orthopedic surgery trial in 2002 at a couple of different meetings. And if you contact me, Doug Sayles, I can give you what's already public. The actual publication of -- in a peer review journal has been in the process of being submitted by investigators now, but there are some abstracts and posters that are available.

Richard Adams - *Bennett Lawrence - Analyst*

Right. I've seen the abstracts that are public, I was just curious about the full comprehensive data set.

Doug Sayles - *Biopure Corporation - Corporate Communications*

It isn't really like a chemical drug, there's an awful lot of data from this trial, and it's a first in class and the only trial of its kind. And part of the issues with the peer review journals is how to get all the information into the word limits. But we're trying to see if whether it can all be fit within the word limits or cut up into multiple publications, and there are various investigators working on that right now.

Richard Adams - *Bennett Lawrence - Analyst*

Just one other. I missed the explanation on the blood transfusion records from the clinical sites. Why the FDA would -- why you thought they were requesting that information?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Remember, this is the first clinical trial ever conducted against blood. So, I think the FDA is interested in getting more information about what the normal transfusion patterns are for various hospitals around the country and specifically our sites. So, it's historical -- it's simply historical data.

Richard Adams - *Bennett Lawrence - Analyst*

But you do think you can supply that or you're not sure at this point?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

We think we can, we just think it's a lot of work. Not that we mind working hard.

Richard Adams - *Bennett Lawrence - Analyst*

Thanks.

Operator

John Cort (ph) of Monarch Financial.

John Cort - *Monarch Financial - Analyst*

Thank you for taking the call. You pointed out in -- of the Section 21 information related to the South African use of the product, and I think we all would like to see. But that aside, how long has -- it's Hemopure that has been actively used in South Africa now? Is that correct?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

It has been actually used, yes? And how long -- we actually began making it broadly available in mid 2002.

John Cort - *Monarch Financial - Analyst*

So let's say a year or so? How many units to your knowledge have actually been dispensed or used by patients?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

A little over 1000 units.

John Cort - *Monarch Financial - Analyst*

So enough to get some semblance of its success as I think you alluded to?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Exactly.

John Cort - *Monarch Financial - Analyst*

Great. I was curious as to -- for obvious reasons now that you've stated it's been very quiet. We know it's in South Africa but we really didn't know exactly what was going on and now we know why. So I thank you very much and continued success.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Thank you, John.

Operator

(OPERATOR INSTRUCTIONS) Richard Aussie of Nation Direct.

Richard Aussie - *Nation Direct - Analyst*

Good afternoon, gentlemen. My question is, what will you do if Biopure doesn't get FDA approval? And if you do get FDA approval, what will be your three and five-year plan? Merge or get more approvals from different countries?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Sure. I'll address your first question first. While we are continuing to be cautiously optimistic, we're on the approval track. If you ask us to specifically address this question, which you have, I guess what I'd say is the FDA doesn't really just say no. At least not in a situation like this where an application has been accepted and taken this far down the review track. What the FDA says is here's what you've got to do, guys, if you want to persuade us to say yes. And generally what they'd say is you need more information. I'm going to take a big leap here, Howard may hit me. But if the information we've given them so far led them to say we can't approve it then they would've already said we can't approve it. Okay? You don't go back and forth like this because the product is not approvable. The question for the agency is the process of putting together the adequacy of the total data set.

So, while we think we will have a more than adequate data set, again your question is what if they say no it ain't adequate. If they said that, they would then tell us what we need to do to be able to get back in front of them to get them to consider it once more. So, what we would do after an event like that is directly related to what the FDA requests. If they requested for instance a new round of animal trials, those can generally be conducted in under six months and so we would say, okay, we'll see you again in April. If on the other hand they say we need a new round of Phase III style human trials, then that would be a much longer duration proposition. We would have to share with our investing public very clearly where we stand so our investors can gauge what the probability is now, the ultimate approval of the product. We need to raise the money necessary to continue to do those trials and to continue to operate, or to pursue an indication -- a different indication for the product based on the other indications we have under development.

But either way, it would take some time to do that. Obviously, we would need to reduce our burn rate so that the amount of money we raised would be no more than what's minimally needed in order to meet the clinical trial needs and other basic needs of the company. And that's something -- while we don't expect that to happen, that's something we fully engaged with in our own internal planning because we're prudent business managers, or at least we like to think we are.

Richard Aussie - *Nation Direct - Analyst*

Sure.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

The second question you asked is, okay, if they say yes what's the plan from there? In broad terms, here's what we would do. One, we would focus on a very successful launch in the U.S. designed to utilize all of our Cambridge, Massachusetts manufacturing capacity as soon as possible. It would be directed towards orthopedic surgery consistent with the indication for which we expect and hope to get approval. It would initially focus on bloodless surgery where the decision has already been made that people will go to extra lengths to avoid getting a blood transfusion from a stranger. But would be designed to branch out pretty quickly across orthopedic surgery in general. Second, we would negotiate with FDA on what it would take to broaden the indication to general surgery. Our belief is that

Phase IV studies and the like should be adequate, but the FDA has not told us it would be, but should be adequate to get us extended to general surgery which would increase the size of our potential market by a high multiple.

Second, we would go-forward with clinical trials which frankly we already have in the planning stage to explore cardiac ischemia, trauma and cancer therapy both in the U.S. and Europe. Which together would increase the size of our market by several times further. We would proceed with getting regulatory approvals -- applications at least in in Europe and probably in the Far East, and seek to create some geographic based licensing situations fairly quickly in areas where we know we would never be able -- capable of marketing the product directly ourselves. And then secondarily, embark on a business development plan where we would selectively evaluate certain indications and determine from the standpoint of maximizing shareholder value whether or not we should choose to partner out for specific indications.

Richard Aussie - *Nation Direct - Analyst*

Well, that's an elaborate plan. I appreciate it, and best of luck with the new product.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Thank you, Richard.

Operator

Jonathan Lui (ph) of Desto (ph).

Jonathan Lui - *Desto - Analyst*

Hi. Congratulations on your quarter and I guess my question is, what has been the average selling price of Hemopure and Oxyglobin? And kind of a related question is, how many units do you need to ship to breakeven? And third of all, what percentage of the orthopedic market do you need to capture to break even?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

Okay. Speaking quickly on that, Oxyglobin has an average selling price of $125 for the 125 milliliter bag. And on a going basis we have a bit of an introductory discount going on now. We'll have an $85 average selling price for the 60 milliliter bag. Hemopure we have not set a selling price yet, either in South Africa or in the U.S. So, at this point in time I don't have an average selling price to give you in that area. When we do we'll release that. Question number two. Helpers? Helpers? The number of units to achieve breakeven on our manufacturing operations, i.e. who have a plant operating at a profit, is about 40,500 units per year. Total corporate basis, that is handling the costs of clinical research, the well-deserved salaries of our key employees and the like, the figure would be higher but that'll be based on how we choose to control those highly variable costs. What we've said publicly is while we can breakeven off the production of our Cambridge facility, with the type of clinical development programs we have in mind, we think it will take the added capacity of the Sumter facility to be in a position as a company where we're turning in a very (indiscernible) profitable performance. Your third question, Jonathan, I apologize, was?

Jonathan Lui - *Desto - Analyst*

What percentage of the orthopedic market do you have to capture in order to achieve your breakeven target?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

The orthopedic market in total is 450,000 units. That is total transfused units in orthopedic surgery per annum. I apologize, that is wrong. It's 1.5 million units in total in orthopedic surgery; 450,000 are used in the bloodless surgery area which is our original initial marketing target. So, of the orthopedic surgery market, which was your original question, Jonathan, we need basically to achieve a stunning and highly aggressive 2.5 percent market share in order to break even on our manufacturing facility. That is the 40,000 units. If we wanted to break even as a company, we probably would have to get up to around a 7 percent market share that is around 100,000 units to be able to do that.

Within this bloodless surgery target of 450,000 units, there we need to achieve something like an 8 or 9 percent share to break even on our manufactured operations, and realistically around a 20 percent share in order to break even as a total company.

Jonathan Lui - *Desto - Analyst*

Just to follow up on that, what would be your roadmap to cash flow positive?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

The roadmap would be successful introduction within orthopedic surgery. Opening of our Sumter facility, which gives us the added capacity to break through this 100,000 unit level. And then frankly once we do that, we can get to a cash positive position reasonably quickly. Our target right now is to be able to do so basically by the end of 2006 if FDA approval is reasonably prompt, or in 2007 if it takes some time for us to finish the discussions with FDA.

Jonathan Lui - *Desto - Analyst*

How do you plan to kind of maintain your funding in the meantime? Because I understand -- I think you're funded through 2004, April?

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

That is correct. That, of course, assumes no revenue beyond a flat Oxyglobin picture. So the building blocks from here would include, number one, with approval we will start getting revenue from Hemopure sales, and while they are not enough to get us to breakeven, if you cut your burn rate from, let's say, currently $11.5 million per quarter down to one or $2 million a quarter, you are not yet breakeven but you're in a much more manageable financial situation.

Two, we do aim to do these regional licensing deals, which will bring in additional revenue both in some cases in upfront payments, in other cases in additional revenue as the product gets introduced. Third, we will probably go into the market for some additional money as well.

Jonathan Lui - *Desto - Analyst*

Okay. Thank you.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

You're welcome.

Operator

Ladies and gentlemen, we have reached the allotted time for question-and-answers. I would now like to turn the conference back over to management for closing remarks.

Thomas Moore - *Biopure Corporation - Chief Executive Officer*

We do feel very positive about the progress we've made in the last three months. As perhaps you can tell from some of the answers we've given to the questions asked, we're actually pretty far down the track in fleshing out our introductory program, following hopefully FDA approval. But for now our focus is on working with FDA to get to the action letter phase as quickly as possible. We continue to be cautiously optimistic that as soon as we get all our answers back in that we'll be in a very good position. Beyond that, we will continue to work to build our Oxyglobin business. We'll be working on international opportunities. I hope we'll be able to close our financing on Sumter sooner rather than later given the critical role that has in the long-term profitability of the company. But in general, we feel like we're making good progress at this time. It's the most exciting time for your company, and everyone here is frankly just plain very turned on and working extremely hard to make this period as productive as possible. Thank you for your support and I look forward to talking again with you all soon.

Operator

This concludes today's conference call. You may now disconnect.